

**METHOD AND COMPOSITION FOR REDUCING THE TOBACCO CONSUMPTION
OF A HUMAN WHILE FRESHENING THE BREATH FROM TOBACCO ODORS**

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BACKGROUND OF THE INVENTION

Field of the Invention

This invention relates to a method and composition for reducing the tobacco consumption of a human while freshening the breath from tobacco odors. More specifically, this invention relates to a composition, containing *Plantago major*, for reducing tobacco consumption while diminishing tobacco odors in the mouth.

Description of Related Art

The use of tobacco products has been shown to be a major health risk affecting all age groups and cutting across all socioeconomic levels. According to the American Heart Association, cigarette smoking is the most important preventable cause of premature death in the United States. Smokers' risk of heart attack is more than twice that of nonsmokers. Cigarette smoking is the biggest risk factor for sudden cardiac death: Smokers have two to four times the risk of nonsmokers. Studies have shown cigarette smoking to be an important risk factor for heart attack. Available evidence also indicates that chronic exposure to environmental tobacco smoke (secondhand smoke, passive smoking) may increase the risk of heart disease.

Studies have also shown that of the estimated 47 million smokers in the United States, more than 32 million report a desire to quit. Nicotine replacement therapy (NRT) has been shown to be safe and effective in helping people stop using cigarettes when used as part of a

comprehensive smoking cessation program. NRT medicines are available as gum and patches over-the-counter and as nasal sprays and puffers ("inhalers") by prescription. The consistent use of one of these products doubles the chances of success with stopping smoking. Behavioral changes and support are essential to success in conjunction with the NRT's and generally, the more intense the behavior modification therapy, the greater the chance of success.

One such product which may be used for helping in the cessation of tobacco product consumption is disclosed U.S. Patent Number 4,284,089 entitled Simulated Smoking Device, issued to Jon P. Ray. Ray discloses a simulated smoking device, adapted for non-burning or non-combustion uses and consists of a container defining a passageway having a vaporizable nicotine source therein. As with tobacco consumption, a product, such as the one disclosed in Ray, suffers from its use of nicotine to prevent the need for tobacco.

Natural products, which may also aid in the reduced consumption of tobacco, have also been proposed. U.S. Patent Number 5,716,635 entitled Plantago Major Transdermal Patch For Use In Treating A Tobacco Or Nicotine Habit, issued to Mary E. Cody discloses a *Plantago major* transdermal patch for use in treating a tobacco or nicotine habit. Similarly, U.S. Patent Number 6,063,401 entitled Plantago Major And Hypericum Perforatum Compound For Use In Treating A Tobacco Or Nicotine Habit, also issued to Mary E. Cody, discloses a *Plantago major* and *Hypericum perforatum* compound for use in treating a tobacco or nicotine habit. The difficulty with the transdermal patch proposed by Cody is that the user must wear the patch continually to deliver the necessary amounts of *Plantago major* extract. This prevents the user from regulating the amount of extract necessary throughout the day.

The compound of 'Cody '401' also discloses a smoking cessation aid including the herb *Plantago major*, but with the addition of *Hypericum perforatum*. The 'Cody '401' composition includes *Hypericum perforatum*, an anti-depressive, to help with the psychological effects associated with nicotine withdrawal after a tobacco user has ceased consuming nicotine-containing products. The disadvantage encountered with this product is the necessity of ingesting an anti-depressive in conjunction with a smoking-cessation aid. Many in the tobacco consuming public might be adverse to the use of an anti-depressive, either due to an aversion to such products or their current use of other medications.

A secondary concern for tobacco consumers, and which may be just as detrimental, is the offensive breath which is commonly evident after tobacco consumption. Not only is the tobacco consumer detrimentally affecting their health, but simultaneously damaging their social interactions due to the offensive odor emitted from their mouths. This additional, psychological effect of tobacco consumption may further compound the health risks encountered by tobacco consumers. In this aspect, it is well known of the large number of breath fresheners available to consumers which attempt to conceal the smell of tobacco. Products which assist in the cessation of tobacco consumption are sometimes formulated with flavored additives, but only for making the product more palatable for the consumer and to cover-up the flavors usually associated with smoking cessation aids.

In light of the prior art, there currently exists a need for a product which assists tobacco consumers in their fight to reduce their tobacco intake while masking the offensive odor which remains after such tobacco consumption.

SUMMARY OF THE INVENTION

One object of the invention is therefore to provide a product which reduces the urge for tobacco consumption.

A further object of the invention is to provide a product which helps diminish the odor which remains in the mouth after consumption of tobacco.

Another object of the invention is to provide for both an aid for the cessation of tobacco consumption while diminishing the odor left in the mouth after said consumption of tobacco.

A further object of the invention is to provide for a method of delivering an aid for cessation of tobacco consumption while simultaneously diminishing the odor of the tobacco consumed.

Accordingly, the present invention provides a composition for reducing tobacco consumption in humans while providing fresh breath comprising *Plantago major* and an additive for diminishing the odor characteristics of tobacco. The additives may be any masking agents, antiseptic agents, neutralizing agents, breath fresheners, mint, licorice, cherry, cinnamon, spearmint, peppermint, anis, garlic, clove, and coffee.

The present invention also provides a method for reducing the consumption of tobacco while providing fresh breath through the oral administration of a composition comprising *Plantago major* and an additive for diminishing the odor characteristics of tobacco.

DETAILED DESCRIPTION

The present invention provides a composition comprising *Plantago major* in combination with a tobacco odor diminishing agent for helping consumers of tobacco reduce, or quit, such

consumption while diminishing the odor of tobacco during the period of reduction in tobacco consumption.

The natural product used in the present invention is extracted from the plant *Plantago major*. *Plantago major* belongs to the *Plantaginaceae* family and is otherwise known as the
5 'common plantain' or the 'great plantain.' The plant consists of a basal rosette of leaves which abruptly contract into long petioles, and have a cylindrical spike of up to 50 cm in height. The extract is derived from the dried leaves of the plant during its flowering period. The extraction process may be carried out using any of the commonly known techniques, such as alcohol and/or water extraction.

10 The beneficial effects of the *Plantago major* extract are derived from the compound aucubin, a pyridine monoterpene alkaloid. This particular glycoside has been shown to exhibit efficacy as a suppressant in tobacco consumption. Additionally, aucubin has been shown to include anti-inflammatory and antispasmodic activity as well as protection of the liver against the toxic effects of chemicals such as carbon tetrachloride, possibly due to the inhibition of
15 cytochrome P-450 activity. *Plantago major* additionally appears to induce a temporary state of relaxation, helping further to mitigate the need for tobacco consumption. Although nicotine has been shown to possess detrimental cardiac effects, *Plantago major*, to date has not been shown to bring about any adverse cardiac side effects.

The *Plantago major* extract of the present invention may be included in a composition
20 meant for oral ingestion. Alternatively, the *Plantago major* extract may be added to the composition of the present invention as a homeopathic preparation. Homeopathic preparations

are based on the therapeutic approach of administering drugs to a person in need thereof, which would normally bring about symptoms, similar to the disease state, in a healthy person. A feature of the homeopathic approach is the administration of the treating composition in very low doses, but sufficient to bring about the desired therapeutic effect.

5 A homeopathic remedy may be diluted and rediluted several hundred times. This method of preparing a remedy is called potentization, whereby a remedy is continually diluted to the point of final dilutions which may be 1 part in 1 million. The preparations are normally at levels which, at pharmacological or toxic doses, cause symptoms that mimic those which are the subject of the treatment.

10 The preparation of *Plantago major* used in the present invention may then be combined with an additive for diminishing the odor characteristics of tobacco. These agents may be, for example, masking agents, neutralizing agents and antiseptic agents. Masking agents are primarily used for covering or hiding smells. These agents do not remove smells but compete with the odors found in the mouth. Examples of masking agents include breath fresheners such as mint, licorice, cherry, cinnamon, spearmint, peppermint, anis, cloves and coffee flavorings:
15 either naturally derived or synthetic.

20 Antiseptic agents partially correlate with the masking agents due to the antiseptic qualities of some of the masking agents. Examples of these antiseptics include some of the essential oils of plants such as mint, spearmint, peppermint and licorice as well as alcohol, thymol, menthol, eucalyptol and methyl salicylate.

 Neutralizing agents, as opposed to the masking agents, effectively remove smells or the

mechanisms which bring about malodor in the mouth. Plaque causing bacteria in the mouth produces malodor due to the acidic byproducts given off through the bacteria's metabolism of carbohydrates. Additionally, residual odor producing molecules are also deposited in the mouth after tobacco consumption and ingestion of certain foods. Agents which assist in the neutralization of acidic conditions brought about by plaque producing bacteria include bicarbonate and effective salts thereof due to their release of neutralizing ions. Citrus flavorings and citric acid also serve to neutralize odors remaining after tobacco or food consumption.

The combined composition may be formulated into an orally ingestible composition and may be, for example, in liquid form, an orally dissolvable tablet or a powder. If the composition is formulated into a liquid form, it may be delivered to the user through a spray.

In a most preferred embodiment, the *Plantago major* extract, in a homeopathic 1X (1:10 dilution) is combined into a formulation with water, a pharmaceutically acceptable base, 8% to 10% ethyl alcohol and a predetermined amount of an odor masking, antiseptic or neutralizing agent such as spearmint, citrus flavoring or thymol. Said formulation is then placed into a pressurized spray canister. The canister is a commonly know spray dispenser, including a cap which releases the contents upon applied pressure from a finger. In use, a person which orally utilizes or consumes tobacco products may spray the product into the mouth.

The product may be used as part of a tobacco utilization cessation program and used at specific or regular intervals throughout the day. Alternatively, if the user has reduced their intake of tobacco products they may then use the product only as the need arises. The tobacco odor diminishing additive, masking, antiseptic or neutralizing agent of the composition of the

present invention is therefore useful to reduce tobacco utilization or consumption as well as mask or neutralize the odor of tobacco or use an antiseptic. As the tobacco use diminishes, the need for the diminishing additive, masking, antiseptic or neutralizing agent also decreases.

The foregoing description of a preferred embodiment of the invention has been presented
5 for purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Obviously, many modifications and variations will be apparent to practitioners skilled in this art. It is intended that the scope of the invention be defined by the following claims and their equivalents.

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